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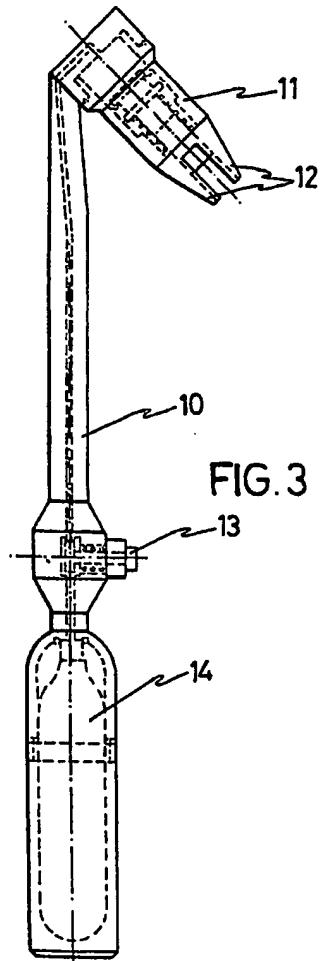
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(54) Vaginal autosuture device

(57) A vaginal autosuture device to treat urinary incontinence in women is disclosed. The device comprises an elongate body 10 having at one of its ends an extension at a specific angle to the horizontal axis of the body. The extension defines a head 11 through which and by means of actuating a manual control 13 a clamp is released or, in other embodiments, a threaded needle is turned. The clamp or threaded needle pass through the para-urethral tissue and the cartilage of the symphysis pubica effecting a connection and lifting of the corresponding areas of the vagina located on both sides of the urethra thus avoiding urinary incontinence.



GB 2 268 690 A

117

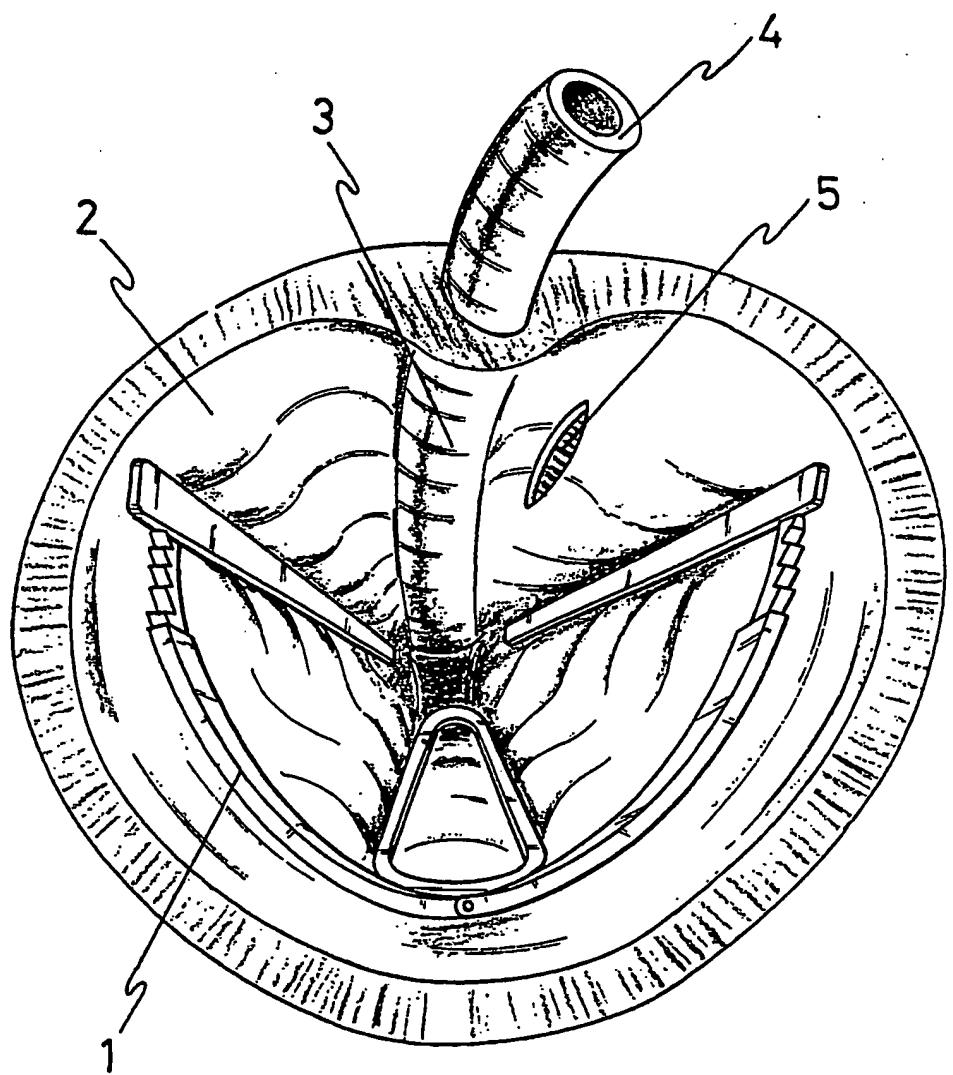


FIG. 1

2/7

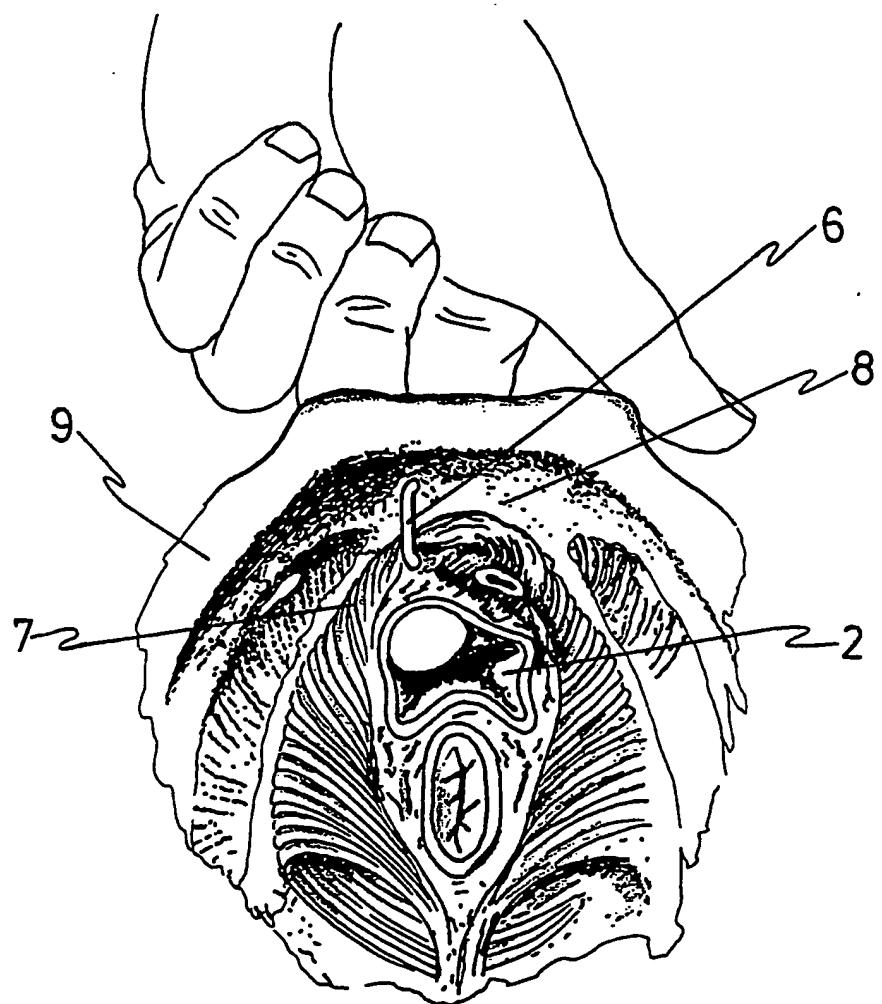
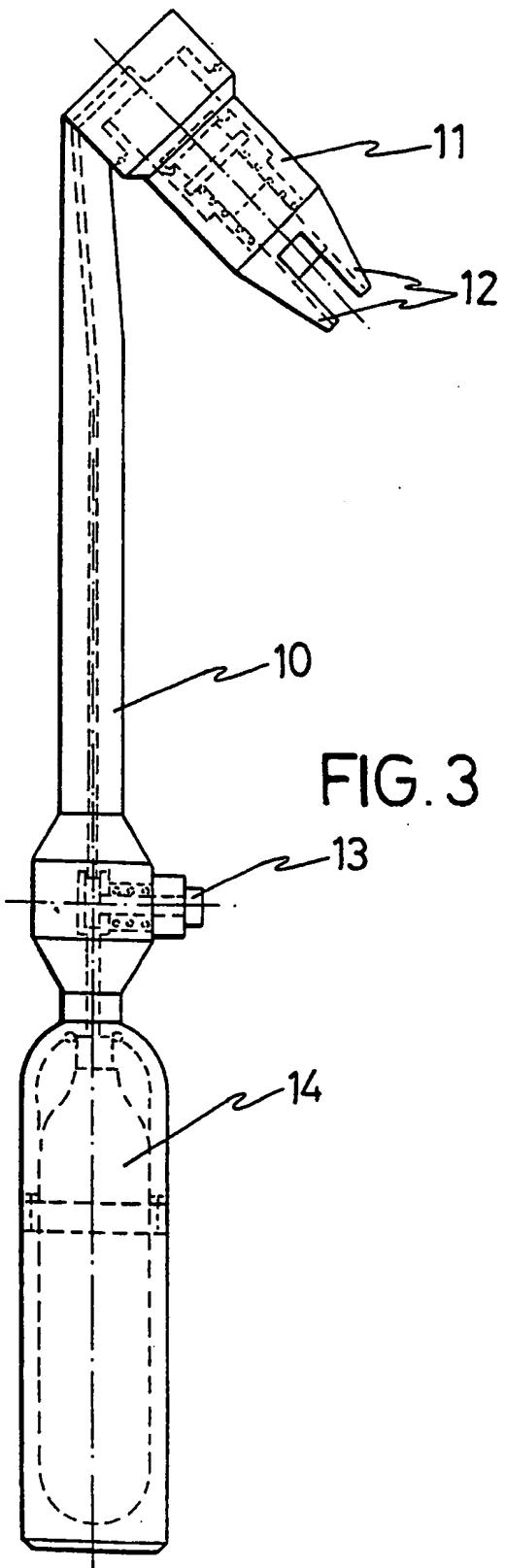


FIG. 2

3/7



4/7

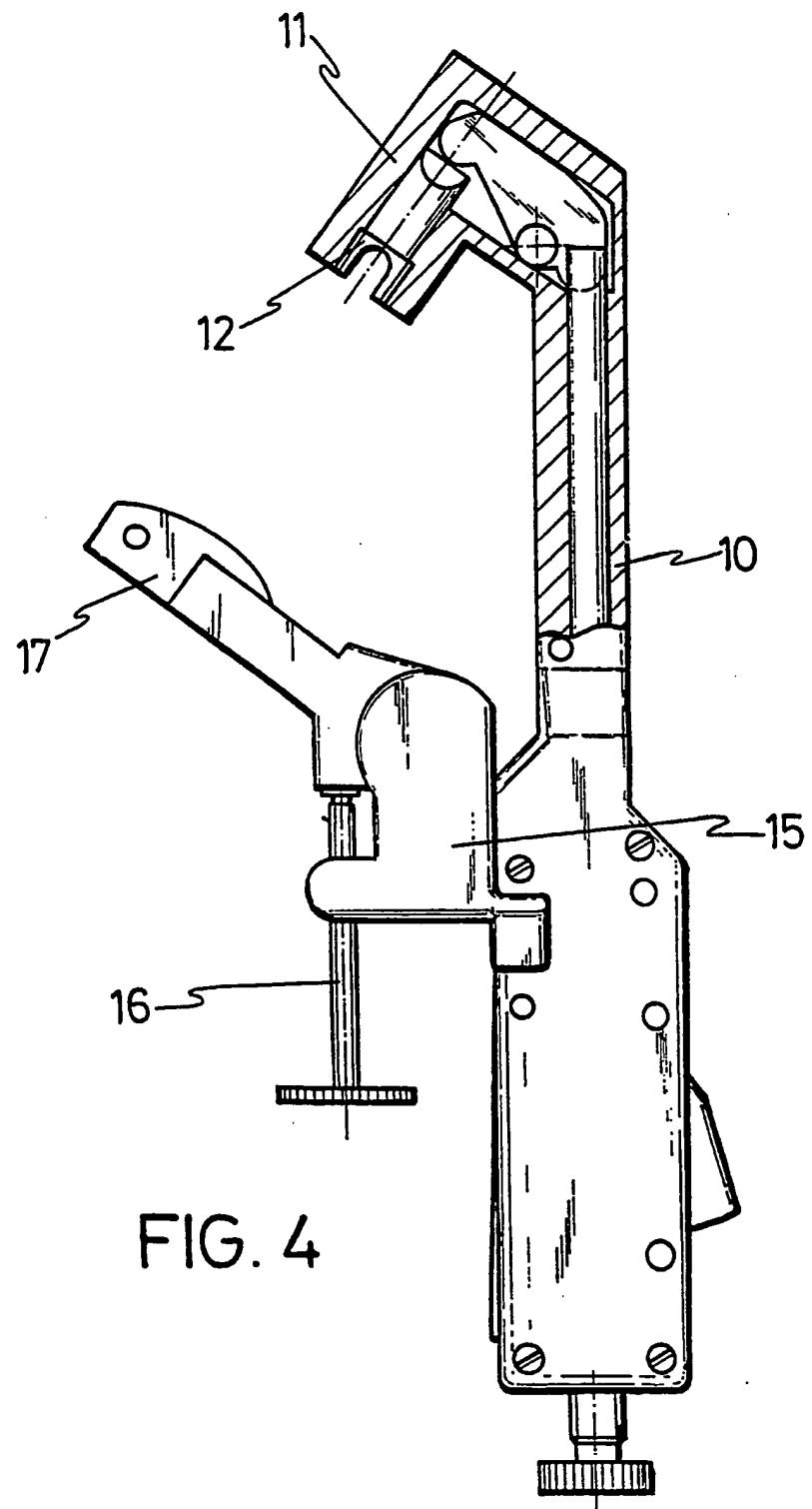


FIG. 4

5/7

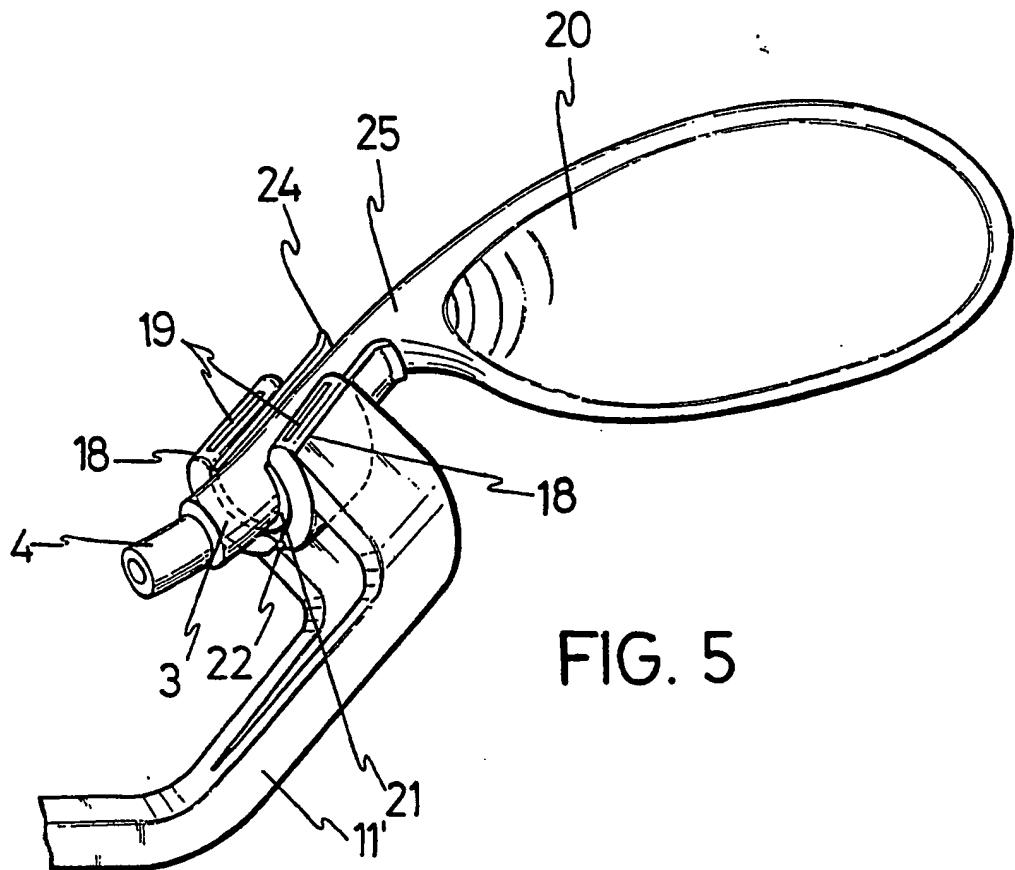


FIG. 5

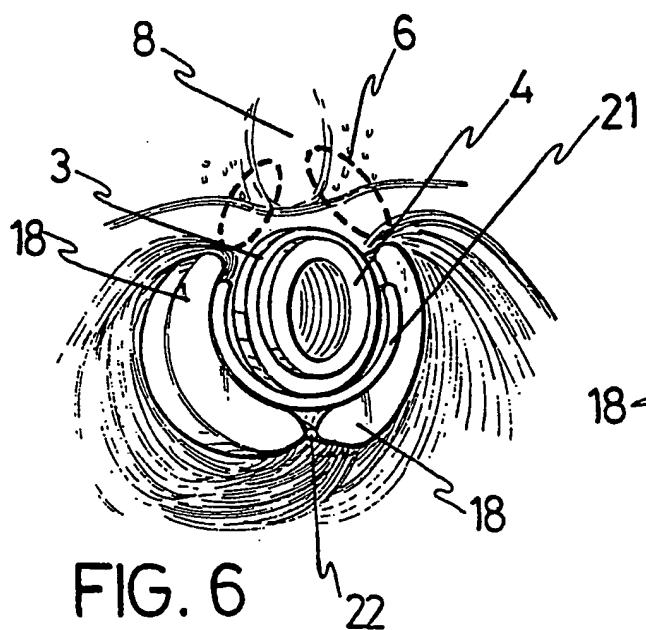


FIG. 6

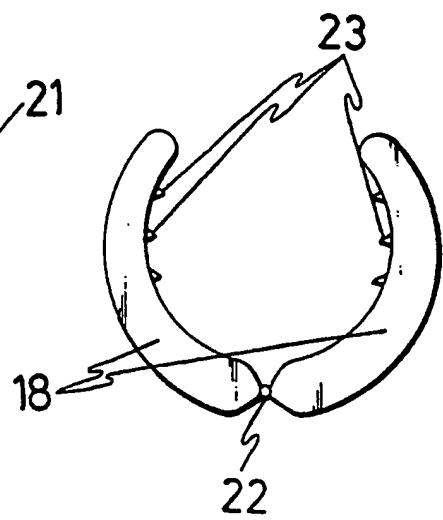


FIG. 7

6/7

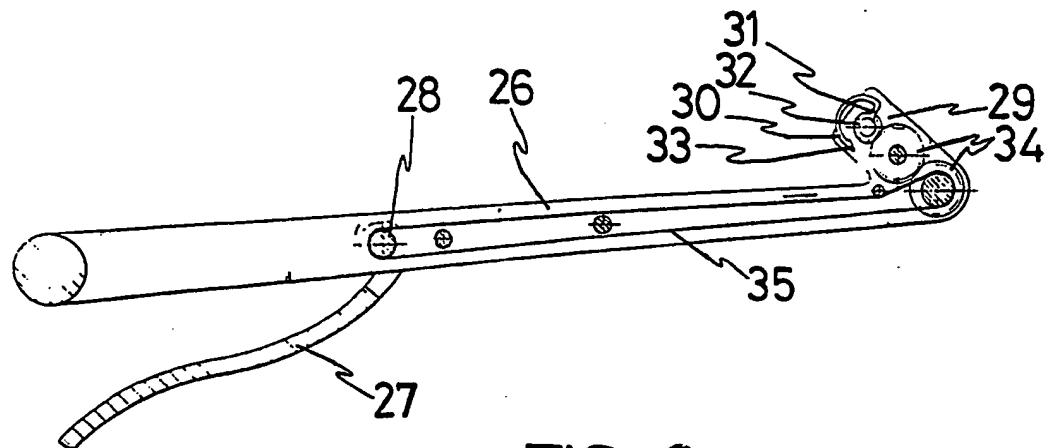


FIG. 8

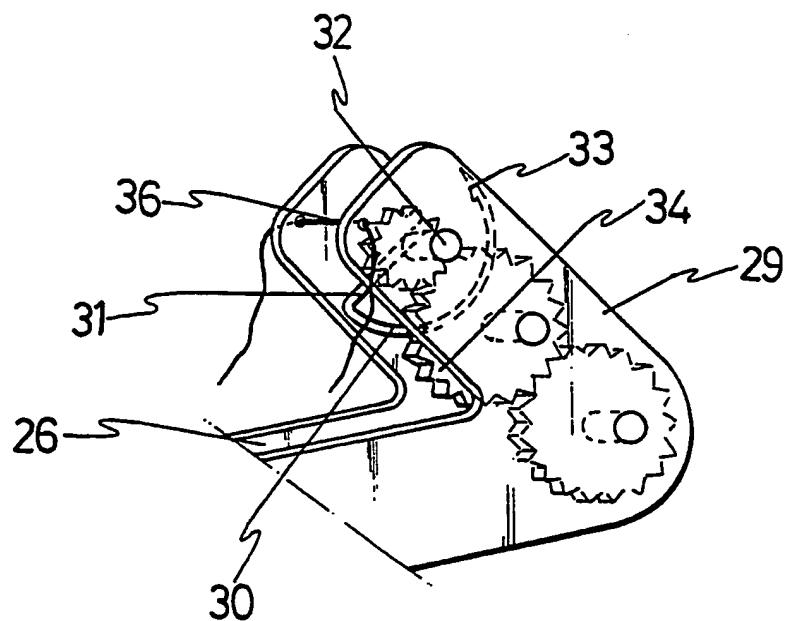


FIG. 9

7/7

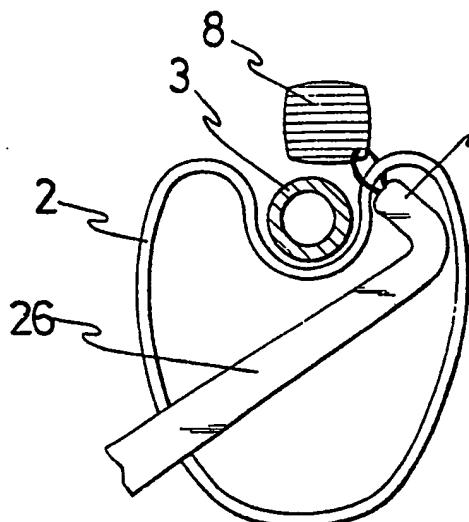


FIG. 10

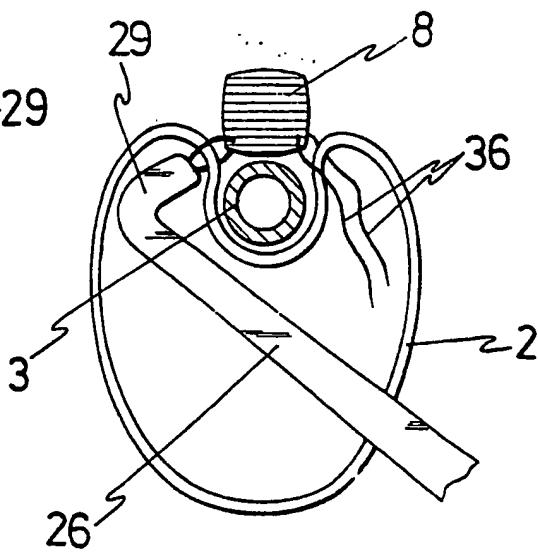


FIG. 11

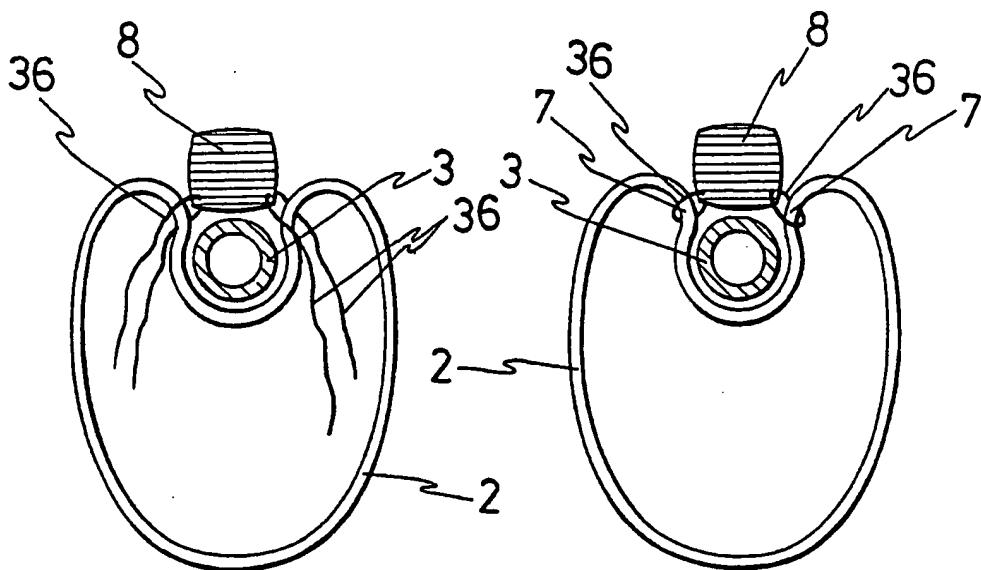


FIG. 12

FIG. 13

VAGINAL AUTOSUTURE DEVICE TO AVOID URINARY INCONTINENCE IN WOMEN

OBJECT OF THE INVENTION

The invention refers to a vaginal autosuture device to avoid urinary incontinence in women, the device being foreseen to carry out by means of clamps or by means of threads connection between the para-urethral parts of the vagina and the corresponding cartilage of the symphysis pubica, for the purpose of fastening and maintaining these para-urethral areas of the vagina permanently raised and thus avoiding urinary incontinence in women.

The device by means of which the autosuture is carried out is comprised of an elongated body handled by the surgeon himself, whose end includes a head through which the release of clamps is carried out, or else the actuation of a needle to make the thread pass through the tissues corresponding to the para-urethral area of the vagina and the symphysis pubica, obtaining in the present case autosuture, and requiring in the second one the knotting of each thread to attain autosuture.

BACKGROUND OF THE INVENTION

As is known, the urethra has its own mechanisms that allow it to interrupt the wave of pressure that is received from the urinary bladder, when the intra-abdominal pressure that comes about suddenly and unexpectedly (for example, cough) acts upon the urinary bladder. The behavior of the anatomical elements that hold it in place are interpreted in very different manners by specialists.

In any case, when the protective mechanisms are changed (delivery and, basically, age) the urethra "descends", while the pelvic diaphragm becomes thinner reducing the urethral resistance, upon the contracting force with which the diaphragm and the sphincter contract being decreased. In this situation, the increased wave of vesical pressure is passed on by the urethra and,

1 depending on the degree of deterioration , the leakage
of urine will be more or less abundant.

5 In order to correct this type of incontinence
normally surgery has been resorted to, based on raising
the urethra and creating an anchorage or inflection point
where the "folding" effect that interrupts the wave of
pressure transmitted from the urinary bladder is produced.

10 There are many praised surgical procedures, some
vaginal and other abdominal, there being others that are
done through both the vagina and the abdomen, so that in
all cases the surgical operation is complex.

DESCRIPTION OF THE INVENTION

15 The object of the invention has the purpose of sol-
ving urinary incontinence in women by means of a very
simple and enormously effective system, based on carrying
out a fastening of the side parts of the urethra upon the
cartilage of the symphysis pubica, so that with the pa-
tient in a gynecological position and with a suitable
vaginal separator, said vaginal cavity is spread open,
20 exposing the roof of this organ where the urethra passes,
examining afterwards the rears of the urethra and vagina
which are the limits between the urethra and the vagina,
which run all along the urethra itself. Afterwards,
a vesical catheter is inserted through the urethra to
25 better examine this duct and afterwards the mobility of
the urethra is explored, detecting the cartilage of the
pubis by the raised part that it normally has with regard
to the bones that delimit it.

30 Consecutively, the fastening of each one of these
side parts of the urethra is carried out by means of the
device of the invention, which is comprised of a clamp-
ing device whose end or whose head through which the clamps
are released will be placed against the posterior surface
of the pubis, so that the actuation of said clamping de-
vice carries out the clamping of the clamp into the carti-

1 lage of the pubis, fastening in this way the urethra upon
fastening the roof of the vagina on each side.

5 By means of the end of the clamping device one can
detect or locate the cartilage of the pubis to fasten
the urethra, on both sides, the clamping device being
pneumatic, in other words, it is operated by compressed
air and it will be provided with the corresponding push
button actuation of which releases the clamp and clamps
it into the cartilage of the pubis to which the wall of
10 the vagina will remain fastened.

Logically, these clamps once clamped into place,
will close to prevent them from coming loose.

15 Likewise, the cited clamps will produce in the tis-
sues involved an adequate compressive effect to bring
about the healing response of the tissues.

20 In the area where the clamps are going to be ap-
plied, it is necessary to make an incision with a sca-
pel in the mucous membrane of the vagina so that upon
inserting the clamp said clamp remains hidden behind
said mucous membrane of the vagina.

25 Locating the cartilage can also be done by radio-
scopy, in which case the clamping device will be made
out of a plastified material, and upon the clamp being
made out of metal the point where the clamp itself is
to be applied will be easy to locate. This second type
of clamp will have an external device with a pressing
effect to better fasten the mouth of the clamping device
against the surface to be clamped, and so that the im-
pact of the clamps is more effective and sure.

30 In a second embodiment it has been foreseen that
the clamping device is completed with a channel adapt-
ted to the mouth of the clamping device for the purpose
of protecting the urethra against strangulations or dam-
age that can be caused in the clamping action, whose chan-
nel will logically go around the urethra, once the ure-

1 thra has been spread open after introducing a urethral
catheter in the same.

5 Said channel has the particularity that the end that
remains in the bottom part is broader in its caliber so
that it can adapt to the funnel that the neck of the uri-
nary bladder forms with regard to the urethra.

10 It is obvious that the element that comprises the
cited channel makes the positioning of the clamping de-
vice easier, since the urethra is obligated by the chan-
nel and upon lifting the clamping device so that it
approaches the pubis the neck of the urinary bladder will
be lifted and moved in order to prevent it from being in-
cluded in the thickness of the tissue that is going to be
clamped.

15 Therefore, on the grounds of this second embodiment
or channel with which the clamping device is complemented,
a correct positioning of said clamping device is achieved,
upon having a better reference upon positioning the clamp-
ing device with regard to the urethra, whereby the clamping
20 will be more exact.

25 It has also been provided for that in this second
embodiment the clamping device is provided with a double
mouth for the purpose of simultaneously applying two
clamps, one on each side of the urethra, in such a way
that one mouth of the clamping device will remain on one
side of the channel and logically the other one will re-
main on the other side, said mouths being oriented angu-
larly with regard to the middle line, in direction to the
cartilage of the pubis, thus making the operation easier,
30 on the contrary to that which would happen with the clamp-
ing device with a single mouth by means of which two opera-
tions would be necessary to apply the two corresponding
clamps.

35 On the other hand, these heads of the clamping device,
aside from being tilttable with regard to the central chan-

1 nel, will have side grooves or striae that permit the
positioning of the channel at different heights, in other
words, the position thereof will be able to be varied in
order to remain closer or farther away from the pubis,
5 to keep the urethra spacious.

In a third embodiment, the autosuture device is
foreseen so that the autosuture is done by means of
thread instead of clamps, the device being provided in
the end of its head with a semicircular needle that is
10 rotated by means of an internal mechanism, such as a
transmission based on a chain and pinions for example,
upon manual operation of an external lever, all in
such a way that the needle turns and its end describes
an arc that in one direction perforates the vaginal wall
15 and the tissue forming the symphysis pubica, while turn-
ing in the other direction involves the threading and
pulling of the thread which, previously placed in a suit-
able area of the head of the device, is clasped by said
semicircular needle, upon the needle having a type of
20 notch in its end, in such a way that by means of the notch,
in the direction considered as a recoiling in the turning
of the needle, the clasping and pulling of the thread that
will be made to pass through the holes that the needle has
previously made in its advance rotation are carried out.

25 In this way, carrying out the operation on both
sides of the urethra, the two ends of the thread will
remain entering and coming out through the openings that
the needle has marked in its path, knotting afterwards.

As it is easy to infer, the tightening of the auto-
30 suture can be gauged since upon the two ends of the thread
remaining loose, before knotting, tightening to a greater
or smaller degree can be done and therefore an adjustment
of the tightening will be achieved, which obviously im-
plies an advantage over the autosuture done with a clamp-
35 ing device wherein no adjustment nor pre-tightening can be

1 done.

DESCRIPTION OF THE DRAWINGS

In order to complete the description that is going to be made hereinafter and for the purpose of providing 5 a better understanding of the characteristics of the invention, the present specification is accompanied by a set of drawings on the grounds of whose figures the innovations and advantages of the device made in accordance with the object of the invention will be more easily 10 understood.

Figure 1.- It shows a representation corresponding to the spreading open of the vaginal cavity done by means of a separator provided for this purpose, likewise representing in this figure the incision in one of the sides 15 of the urethra, in whose incision precisely the corresponding clamp will be applied by means of the device of the invention.

Figure 2.- It shows a general perspective view of the inside of the vaginal cavity where one can see one 20 of the two clamps that are to fasten the sides of the urethra to the pubis.

Figure 3.- It shows a longitudinal and schematic view of the device that comprises the metal clamping device for carrying out the surgical autosuture that forms 25 part of the object of the invention.

Figure 4.- It shows the clamping device made out of transparent plastic material, it being actuated mechanically to release the clamps.

Figure 5.- It shows a representation according to 30 a general perspective view of the head of the clamping device in its second embodiment, in other words, provided with the urethra support channel, also showing the catheter and the corresponding urinary bladder.

Figure 6.- It shows a front perspective view of 35 the clamping device represented in the previous figure,

1 supporting the urethra fastening channel, as well as the
clamps in dash lines.

Figure 7.- It shows a detailed view of the double
head of the clamping device represented in the two pre-
5 vious figures, with the corresponding internal striae
to permit the positioning of the corresponding urethra
support channel at different heights.

Figure 8.- It shows a longitudinal sectional view
of the device in another embodiment, foreseen so that the
10 autosuture is done by means of thread, the head of the
device having for this purpose a semicircular needle that
is rotated and operated by means of a mechanism based on
pinions and a chain, actuated by a hand control.

Figure 9.- It shows a detailed view of the head
15 of the device represented in the previous figure, where
one can clearly see the assembly of the needle and a
possible positioning of the thread to be clasped by the
end of the needle.

Figures 10, 11, 12 and 13. They show other sche-
20 matic views of what can be considered the vagina, ure-
thra and one part of the cartilage of the symphysis pu-
bica, said figures showing the different stages to carry
out the autosuture between the vaginal cavity and the
cartilage of the symphysis pubica, on both sides of the
25 urethra, and whose autosuture is done by means of the
device represented in figures 8 and 9.

DESCRIPTION OF THE PREFERRED EMBODIMENT

In view of the cited figures, and alluding first of
all to figures 1 and 2, for use of the device by means
30 of which the autosuture is going to be done, it is neces-
sary to place the patient in a gynecological position
first of all, so that by means of a vaginal separator (1),
formed by a body with two arms hinged together and con-
nected in common to a positioning element, as is repre-
35 sented in figure 1, the vaginal cavity (2) is spread open,

1 exposing the roof of the vaginal cavity where the urethra
(3) passes, examining afterwards the rears of the urethra
and vagina which are the limits between the urethra and
the vagina, which run all along said urethra (3.)

5 Afterwards a vesical catheter (4) is inserted through
the urethra itself (3), to better examine this duct, ex-
ploring afterwards the mobility of the urethra, which is
easier to examine as the catheter (4) is incorporated, it
being possible to detect the cartilage of the pubis by
10 the raised part that it normally has with regard to the
bones that delimit it.

In figure 2, the exploration and even a clamp (6)
fastened to one of the sides of the urethra (3) can be
seen, the clamp (6) that will remain contained in an in-
15 cision (5) made with a scapel in the suitable area, to
achieve that the clamp (6) is hidden, it being possible to
see in figure 2 how said clamp (6) raises the area corres-
ponding to the para-urethral tissue (7) and holds it in
that raised position upon the other end of the clamp (6)
20 clamping into the pubic ligament corresponding to the bone
of the pubis (9), in other words, in the tissue that forms
the symphysis pubica.

In figure 3 the clamping device by means of which
the above cited autosuture is carried out is seen, so
25 that this clamping device is comprised of an elongated
body provided in one of its ends with a head (11) that
forms an angular extension with regard to the horizontal
axis of the body (10) of the clamping device, and whose
head (11) will rest on the above cited previously located
30 points, that correspond to those of making the incisions
(5), for which purpose that head (11) of the clamping
device will slide over the posterior wall of the pubis
to detect the raised part of the cartilage of the sym-
physis pubica, and once this operation has been carried
35 out and having the sensation that the cartilage has been detected,

1 before inserting the clamp (6) the clamping device will
be removed and the incision (5) will be made with the
scapel, incision that is made in the mucous membrane of
the vagina, right in the place where the mouth corres-
5 ponding to the head (11) of the clamping device (10)
rests, with the intention that upon inserting the clamp
(6) said clamp remains hidden behind the mucous membrane
of the vagina.

Therefore, the ends (12) of the head (11) of the
10 clamping device will be inserted in the bed formed by
the incision (5) going over the bone of the pubis until
the cartilage of the symphysis pubica is found again and
in this position by means of a push button (13) the cor-
responding clamp (6) will be released, joining or fasten-
15 ing the wall itself of the vagina to the cited cartilage.

The clamping device shown in figure 3 is operated
pneumatically, including for this purpose an inside car-
boy (14) in its corresponding handle, so that the pres-
sure of the gas contained in the carboy releases the
20 corresponding clamp (6) and the clamp clamps into the
cited area.

In figure 4 a clamping device (10) that will be made
out of transparent plastic is seen and it will make it
possible to locate the area where the clamp (6) is to be
25 placed, upon the clamp being made of metal, with the help
of radiographic amplifying equipment so that under the
control of radioscopy the effective end (12) of said
clamping device (10) is viewed, logically this end will
have the clamp and as the same is made out of metal the
30 same is easy to locate, leading same to the transparent
space between the bones of the pubis that correspond to
the cartilage of the symphysis pubica. Once this posi-
tion has been reached an element or mechanism that is
assembled upon the clamping device itself and that is
35 a pressing mechanism will be actuated, permitting the

1 gripping of the cartilage of the pubis. This mechanism
is comprised of a fastening support (15), to which the
pressing element itself (17) is connected, this press-
ing device being adjustable by means of a manual opera-
ting screw.

5 In a second embodiment, as is seen in figures 5, 6
and 7, the clamping device includes a head (11') divided
into two parts or identical heads (18), each one of them
provided with a outlet mouth for the corresponding clamp
10 (6), all so that by means of this embodiment it is pos-
sible to simultaneously apply the two clamps, one on each
side of the urethra (3), and the urethra having inside it
the corresponding catheter (4), and continuing, as is
seen in figure 5, in the corresponding urinary bladder
15 (20.)

The heads (18) referred to and shown in figures 5,
6 and 7, and therefore the corresponding outlets (19)
remain located one on each side of a channel (21) located
between said heads (18), supporting these heads, with
20 the particularity that said heads (18) are connected to-
gether by means of a bottom hinge (22), including on the
inside surfaces thereof some longitudinal striae (23)
that permit the channel (21) to be positioned higher or
lower, in order to bring it close to or leave it more
25 distant from the urethra itself (3.)

This channel (21) remains surrounding the urethra
itself (3) as is clearly seen in figure 6, offering the
end of the channel an expansion (24) in order to adapt
to the funnel (25) that the neck of the urinary bladder
30 (20) forms with regard to the urethra (3.)

In this way simultaneous application of the two
clamps (6) one on each side of the urethra (3) can be
carried out, with a direction as is represented in fi-
gure 6, whose clamps (6) will fasten upward the para-
35 urethral tissue of the vagina to the symphysis pubica

1 or cartilage of the pubis (8.)

On the grounds of all of the above, in other words, in connection with the embodiment shown in figures 5, 6 and 7, one manages to apply the clamps (6), carrying out 5 all the operations without the urethra (3) being strangled, since the channel (21) located between the heads (18) will prevent it, aside from permitting the simultaneous application of the two clamps (6.)

In a third embodiment, represented in figures 8 to 10 13, the device of the invention is comprised, as in the previous cases, of an elongated body (26) with a manual operating control (27), like a lever, that emerges from the side part of said body (26), the lever (27) being hinged in a transversal shaft (28.)

15 The body (26) includes the corresponding end head (29) that likewise forms an angle with the horizontal axis of this body, and in whose head a semicircular shaped needle (30) is mounted so as to turn in either direction, and one of whose ends extends into a straight section (31) 20 through which it is fastened to a rotation shaft (32), while at the other end the needle (30) has a notch defining a clasping end (33) as will be put forth later on.

The device includes inside a system to carry out the turning of the needle (30), the system being based 25 on a set of crowns or gears (34) that are operated by a chain (35) which in turn is geared to a pinion assembled on the shaft itself (28), in such a way that actuation of the lever (27) entails rotation of this shaft (28) and therefore the pulling of the chain (35) that will 30 make the gear mechanism (34) turn carrying out the turning of the shaft on which the needle (30) is assembled.

With the device described corresponding to the embodiment shown in figures 8 and 9, the autosuture is done by means of a thread (36), which will replace the above 35 cited clamps (6), in such a way that this thread (36)

1 duly positioned in the head (29) of the device or body
(26), and with the correct positioning of the head in
the same way as it has been said above, actuation of the
lever (27) will carry out the turning of the needle (30)
5 in one direction, turning which will be sectorial until
the end (33) surpasses the thread (36), to later carry
out the turning in the opposite direction, in which
case the end (33) of the needle (30) clasps, by means
of the notch provided for in that end (33), the thread
10 (36) pulling it and making it pass along the path fol-
lowed by the needle (30), and specifically by its end
(33), so that this path is followed, as it has been
said above, through each one of the areas collateral
15 to the urethra (3) and through the cartilage (8) of
the symphysis pubica, as is clearly represented in the
different stages shown in figures 10, 11, 12 and 13.

In other words, what the device does is that by
means of the needle (30) provided for in the head (29) of
the same, it makes a suture thread (36) pass through
20 the para-urethral area (7) of the vagina (2) and through
the cartilage (8) of the symphysis pubica.

As is seen in figures 10, 11, 12 and 13 the opera-
tion is carried out on each side of the urethra (3),
so that with the turning of the needle (30) in one
25 direction and the other, as it has already been said
above, the thread (36) passes through the holes made in
the path of the end (33) of the needle (30), the ends
of the thread (36) remaining free to be subsequently
knotted.

30 Now then, before the first thread (36), placed
on one side of the urethra (3), is knotted, it is
necessary to make the second thread pass to the other
side of said urethra, just as it is shown in figure 12,
35 so that once the two threads (36) have passed through
the respective areas of the wall of the vagina and of

- 1 the cartilage of the symphysis pubica the same will be knotted, it being possible to adjust the tightening by simply tensing to a larger or smaller degree, by simple pulling of the ends of the thread (36.)
- 5 The fact that the thread (36) is not knotted until the other one has been put in place, is because that in order to carry out the operation it is necessary to move the urethra (3) towards the opposite side, operation that can be done with the thread unknotted, since if it were 10 knotted, side movement of said urethra (3) could not take place.

15 The semicircular needle (30) can be placed in the position shown, effecting the turning of said needle in such a way that its end goes along the path from top to bottom, or else upon being located in the opposite position, in which case the end of said needle will go along the path from bottom to top.

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CLAIMS

1.- Vaginal autosuture device to avoid urinary in-
continence in women, which having the purpose of joining
through the vagina the para-urethral tissue of the vagina
5 to the symphysis pubica, and specifically to the connect-
ing cartilage, effecting a spreading open of the vaginal
cavity (2) by means of a separator (1), as well as ex-
ploration of the mobility of the urethra (3) in order to
detect the cartilage (8) of the pubis (9), and the auto-
10 suture being foreseen to achieve the fastening of the
roof of the vaginal wall (2) of each side of the urethra
(3) to the part of the cartilage (8) corresponding to the
posterior surface of the pubis (9), essentially charac-
15 terized in that upon being comprised of an elongated body
(10, 26) extended by one of its ends into a head (11, 29)
that forms an acute angle with the elongated body defining
the means to grip the body by hand; with the particularity
that in the inside of said body means have been provided
for, whose actuation by means of a push button or lever
20 (13, 27), provides the suitable movement so that the auto-
suture element (6, 36) passes through the para-urethral
tissue (7) of the vagina and of the cartilage (8) corres-
ponding to the symphysis pubica, fastening the para-ure-
thral areas of the vagina (2) raised up.

25

2.- Vaginal autosuture device to avoid urinary in-
continence in women, according to claim 1, characterized
in that the elongated body (10) of the device with its
corresponding head (11) constitutes a pneumatically opera-
ted clamping device, storing in its head (11) the corres-
30 ponding clamps that are released through the ends (12) of
said head, after actuating by hand the push button (13)
provided for in the elongated body (10) of the clamping
device.

35

3.- Vaginal autosuture device to avoid urinary in-
continence in women, according to claim two, characteri-

1 zed in that the clamping device (10) is comprised of a
transparent plastic material, making it possible to ap-
ply the clamp (6) under the orientation of radioscopy,
with the particularity that a pubis pressing mechanism
5 can be assembled on the body (10) of the clamping de-
vice, this mechanism being comprised of a support (15)
through which the assembly of the same on the body (10) of
the clamping device is done, support (15) which includes
the corresponding pressing element (17) that is pushed
10 by a manual operating screw (16.)

4.- Vaginal autosuture device to avoid urinary in-
continence in women , according to the above claims, char-
acterized in that the head of the clamping device is
comprised of an element (11') in which two parts or heads
15 (18), each one of which provided with an outlet mouth (19)
for the respective clamps (6), are formed, there being
a channel (21) for positioning and supporting the corres-
ponding urethra (3); it being provided for that said heads
(18) are connected together by means of a bottom hinge
20 (22), the mouths (19) of the heads having a converging
slant in order to apply the corresponding clamps (6)
with a specific angulation that permits the correct
fastening of the para-urethral tissue to the cartilage
of the pubis.

5.- Vaginal autosuture device to avoid urinary in-
continence in women, according to claim 4, characterized
because the channel (21) located between the heads (18),
has in its outside end an expansion (24) to adapt to the
funnel (25) that forms the neck of the urinary bladder
30 (20) with regard to the urethra (3.)

6.- Vaginal autosuture device to avoid urinary in-
continence in women, according to claims 4 and 5, charac-
terized in that the heads (18) include in their inside
surface some projections (23) that permit the positioning
and retaining at different heights the channel (21),
35 making it possible to reduce or increase the proximity

1 of the outlet mouths (19) of the clamps (6) keeping the
urethra (3) without strangulation.

7.- Vaginal autosuture device to avoid urinary in-
continence in women, according to claim 1, characterized
5 in that the head (29) of the elongated body (26) includes
in its end a semicircular needle (30) that, through a
straight arm (31) with internal radial orientation to the
arc of the needle (30), it is connected to a shaft (32)
capable of turning sectorially in both directions, so
10 that the turning in one direction involves the end (33)
of the cited needle (30) emerging through the mouth of
the head (29) and perforating the corresponding para-
urethral area (7) of the vagina (2) and the cartilage
15 (14) of the symphysis pubica, with the particularity
that in the opposite direction of rotation of this
needle (30), a notch shape provided for in the end
itself (33) of the needle, clasps and pulls the suture
element formed by a thread (36) adequately located in
the inside of the head (29) of the device (26), said
20 thread (36) passing through the holes made by the needle
(30) in its path.

8.- Vaginal autosuture device to avoid urinary in-
continence in women, according to claim 7, characterized
because the actuation means of the assembly shaft (32)
25 of the needle (30), are comprised of a system of gears
(34) and a chain (35) that is actuated by a pinion as-
sembled on the rotation shaft itself of the manually
operated lever (27.)

9.- Vaginal autosuture device substantially as
30 herein before described with reference to the drawings
herein.

Patents Act 1977

Examiner's report to the Comptroller under Section 17
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Databases (see below)

(i) UK Patent Office collections of GB, EP, WO and US patent specifications.

(ii)

Documents considered relevant
following a search in respect of
Claims :-
1-9

Categories of documents

X: Document indicating lack of novelty or of inventive step.

P: Document published on or after the declared priority date but before the filing date of the present application.

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| Category | Identity of document and relevant passages | | Relevant to claim(s) |
|----------|--|---------------|----------------------|
| X | GB 1243808 (US SURGICAL) | Note Figure 1 | 1 at least |

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